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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,979	10/20/2005	Nobutaka Nakashima	081356-0253	7959

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EXAMINER	
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ART UNIT	PAPER NUMBER
1636	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,979	NAKASHIMA ET AL.	
	Examiner	Art Unit	
	MICHELE K. JOIKE	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☒ Claim(s) *6-9* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group 3 in the reply filed on February 13, 2008 is acknowledged. However, the Examiner is withdrawing the restriction requirement. Claims 1-9 are pending and examined.

Priority

It is acknowledged that a certified foreign priority paper has been received, Japanese application 2003-116280. However, it is noted that an English translation has not been provided.

Specification

The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers. These sequences include the sequences listed in the claims and throughout the specification. Nucleotide sequences with 10 or more nucleotides and amino acid sequences with 4 or more amino acids require sequence identifiers. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant

application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Figures 9(b-e), 10, 12, 13, 15, 16, 17 ad 19 contain sequences without sequence identifiers.

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Paragraph 153 contains the hyperlink.

Color Drawings

Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the

following language as the first paragraph of the brief description of the drawings section of the specification:

> The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Applicant's petition is denied because the specification is found to be deficient. The first paragraph of the brief description of drawings does not include the above language.

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633

Claim Objections

Claims 6-9 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 6-9 not been further treated on the merits. The claims depend on claim 4, which depends on claims 1, 2 or 3.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank accession number AB127601.

Applicants are claiming a pNit-QT2 vector represented by SEQ ID NO: 100. According to Ex. 9 of the specification, the pNit-QT2 vector is a constitutive expression vector for a bacterium belonging to the genus Rhodococcus comprising: a promoter sequence for the constitutive expression of a foreign gene; a ribosome-binding site sequence located downstream of the promoter sequence; and a multiple-cloning site type 2 sequence, located downstream of the ribosome-binding site sequence.

GenBank accession number AB127601 teaches the pNit-QT2 vector. Direct submission of the sequence occurred on December 2, 2003.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,164,305.

Applicants claim a nucleotide sequence represented by SEQ ID NO: 107, and expression vectors with nucleotide sequences represented by SEQ ID NOs: 99-106. The nucleic acid sequences are only "represented by" the sequence identifiers, therefore the Examiner is interpreting this to mean that any nucleic acid can "represent"

SEQ ID NO: 107, and any expression vector comprising a promoter sequence for the constitutive expression of a foreign gene; a ribosome-binding site sequence located downstream of the promoter sequence; and a multiple-cloning site type 2 sequence, located downstream of the ribosome-binding site sequence can represent SEQ ID NO: 99, 100, 101, 102, 103, 104, 105 or 106.

US 5,164,305 (specifically column 1, line 66 - column 2, line 24) teaches an expression vector with the TipA promoter. The promoter has been mutated by inserting a base between positions -62 and -63 to increase promoter strength. Therefore, the vector in US 5,164,305 represents SEQ ID NOs: 99-106, the mutated TipA promoter represents SEQ ID NO: 107.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,164,305 as applied to claims 3 and 5 above, and further in view of Jaurin et al.

Applicants claim a TipA promoter that has been mutated in the -10 region from CAGCGT to TATAAT.

US 5,164,305 (specifically column 1, line 11 - column 2, line 24) teaches an expression vector with the TipA promoter. The promoter has been mutated by inserting a base between positions -62 and -63 to increase promoter strength, which results in increased protein expression. It does not teach a mutation in the -10 region. It does teach that the -10 region is one of the major determinants of promoter strength, and that most mutations that affect promoter strength map to the strongly conserved bases in the -10 region.

Jaurin et al (EMBO 1(7): 875-881, 1982, specifically p. 875) teach mutating the -10 region from TACAAT to TATAAT.

The ordinary skilled artisan, desiring to change the -10 region from CAGCGT to TATAAT, would have been motivated to combine the teachings of US 5,164,305 teaching an expression vector with the TipA promoter with the teachings of Jaurin et al teaching mutating the -10 region from TACAAT to TATAAT because Jaurin et al teach that changing the -10 region to TATAAT increased promoter strength 7-fold. It would have been obvious to one of ordinary skill in the art to change the -10 region to TATAAT because US 5,164,305 teaches that the -10 region is one of the major determinants of

promoter strength, and it would be natural to change the -10 region that has a non-TATA-box sequence to a TATA-box sequence like TATAAT because it is a strongly conserved sequence that increases gene expression. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takano et al in view of US 5,164,305, and in further view of Jaurin et al.

Applicants claim an expression vector comprising a TipA promoter sequence mutated in the -10 region for the constitutive expression of a foreign gene; a ribosome-binding site sequence located downstream of the promoter sequence; and a multiple-cloning site type 2 sequence, located downstream of the ribosome-binding site sequence.

Takano et al (Gene 166: 133-137, 1995, specifically p. 133 and figure 1) teach an expression vector with the TipA promoter, an RBS downstream of the promoter and a MCS downstream of the RBS. It does not teach a mutated TipA promoter.

US 5,164,305 (specifically column 1, line 11 - column 2, line 24) teaches an expression vector with the TipA promoter. The promoter has been mutated by inserting a base between positions -62 and -63 to increase promoter strength, which results in increased protein expression. It does not teach a mutation in the -10 region. It does teach that the -10 region is one of the major determinants of promoter strength, and that

most mutations that affect promoter strength map to the strongly conserved bases in the -10 region.

Jaurin et al (EMBO 1(7): 875-881, 1982, specifically p. 875) teach mutating the -10 region from TACAAT to TATAAT.

The ordinary skilled artisan, desiring to change the -10 region from CAGCGT to TATAAT, would have been motivated to combine the teachings of US 5,164,305 teaching an expression vector with the TipA promoter with the teachings of Jaurin et al teaching mutating the -10 region from TACAAT to TATAAT because Jaurin et al teach that changing the -10 region to TATAAT increased promoter strength 7-fold. It would have been obvious to one of ordinary skill in the art to change the -10 region to TATAAT because US 5,164,305 teaches that the -10 region is one of the major determinants of promoter strength, and it would be natural to change the -10 region to one that is strongly conserved. Given the teachings of the prior art and the level of the ordinary skilled artisan at the time of the applicant's invention, it must be considered, absent evidence to the contrary, that said skilled artisan would have had a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michele K Joike, Ph.D./

Michele K Joike, Ph.D.
Examiner
Art Unit 1636